

REMARKS

Claims 58, 59, 61-69, and 71 are currently pending in this application. In the Office Action mailed on October 7, 2008 ("Office Action"), claims 58, 59, 61-69, and 71-74 were rejected. Through this amendment, Applicants have amended independent claim 58. Claims 72-74 have been canceled without prejudice. No new matter has been entered. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

I. Claim Rejections— 35 USC § 103(a) – Koros in view of Allen in view of Ouchi

Claims 58, 59, 61-69 and 71 were rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 5,795,291 to Koros ("Koros") in view of US Patent No. 5,733,288 to Allen ("Allen") in view of US Patent No. 5,899,850 to Ouchi ("Ouchi"). Applicants respectfully traverse this rejection as set forth below.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Claim 58, as amended, describes a method for removing intervertebral disc material. The

first step involves creating a working channel from a patient's skin to an intervertebral disc space. The second step involves positioning a protector near an entrance into the intervertebral disc space between a brush member and at least one of neural tissue, dura tissue, and vasculature adjacent to the entrance. The protector has a longitudinal axis and includes a retractor having at least two planar, generally parallel blade members *fixed in position relative to one another to form a generally V-shaped construct* for establishing a barrier between the brush member and the body tissue adjacent to the entrance. The construct has a longitudinal axis extending in a generally parallel orientation relative to the longitudinal axis. The third step involves inserting a brush member into the intervertebral disc space, wherein the brush member has a length ranging from 0.25 to 4.0 inches, a diameter ranging from 0.082 to 1.225 inches, and a plurality of bristle members disposed in a helical configuration defining a capacity for carrying intervertebral disc material. The fourth step involves manipulating the brush member within the intervertebral disc space to receive intervertebral disc material within the brush member. The fifth step involves removing the brush member from the intervertebral disc space.

None of the Koros, Allen or Ouchi references, alone or in combination, appear to teach or disclose each and every element found in claim 58, such that the rejection under 35 USC §103 should be withdrawn. More particularly, Koros, Allen, and Ouchi fail to teach or disclose the limitation of claim 58 where the blade members are *fixed in position relative to one another to form a generally V-shaped construct*. Koros discloses a surgical retraction assembly including a plurality of blades extending generally perpendicularly from a rack (Fig. 1). Notably, the blades are moveable relative to one another so as to expand an incision into an operative corridor (Col. 3 lines 35-67). The blades are not provided in a fixed orientation relative to one another, and furthermore to do so would be contrary to the teachings of Koros, since one would be unable to satisfactorily expand an incision with blades that were fixed in position relative to one another.

Neither Allen nor Ouchi cure the defect of Koros. The Allen reference does not appear disclose any kind of protector, much less one in which the blade members are fixed in position relative to one another to form a generally V-shaped construct.

Ouchi fails to cure the aforementioned deficiencies in what was fairly taught by Koros and Allen. Ouchi may disclose a cover tube (Fig. 16, ref. 5) that encloses the brush portion (Fig. 16, ref. 2). However, Ouchi does not disclose a protector having generally rectangular, planar blade members *fixed in position relative to one another to form a generally V-shaped construct* as claimed by Applicant. Ouchi discloses a cover tube that is made up of arc segments curving toward the brush portion (Fig 4, ref. 14A). The Ouchi cover tube contains slits (Fig. 4, ref. 6) forming **openable portions** (Fig. 4, ref. 14A) that are able to move relative to one another. Thus, Ouchi fails disclose a protector having generally rectangular, planar blade members fixed in position relative to one another to form a generally V-shaped construct as claimed by Applicant.

For at least this reason, one of ordinary skill in the art would not have been motivated to combine the Koros, Allen and Ouchi references, nor would such a combination have led them to arrive at the present invention as claimed. Because Koros, Allen and Ouchi fail to teach or disclose each and every claimed feature in the independent claim 58, Applicants respectfully submit that the rejection under 35 USC § 103(a) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited. Claims 59, 61-69 and 71, being dependent upon and further limiting claim 58, should be allowed for the reasons set forth above in support of the allowability of claim 58, as well as the additional features they contain. Applicants respectfully request that the rejection of claims 58, 59, 61-65, and 67-69 be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney or the attorney of record so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: /jaybell/
Jay B. Bell, Esq.
Registration No. 58,551
Tel: (858) 909-1853

For: Jonathan Spangler, Esq.
Registration No. 40,182
Tel.: (858) 243-0029

7475 Lusk Boulevard
San Diego, CA 92121

January 7, 2009